

DETAILED ACTION

1. No claims have been amended.

Claims 8-14 and 20 have been cancelled

Claims 1-7 and 23 withdrawn from further consideration pursuant to 37 CFR

1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 12, 2007.

2. Claims 15-19, 21, 22, and 24-28 are under examination.

Rejections Withdrawn

3. The rejection of claims 24-28 under 35 U.S.C. 112, first paragraph as requiring a deposit of biological materials is withdrawn in view of applicant's declaration regarding the deposit of the FERM BP-5233 antibody.

Rejections Maintained

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The rejection of claims 26 and 27 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting the term "gene" is maintained.

Applicant's arguments filed July 14, 2009 have been fully considered but they are not persuasive. The response states that applicants respectfully submit that one of ordinary skill in the art would recognize what gene encodes the anti-HM1.24 antibody. This is true especially in light of the fact that applicants have deposited the hybridoma FERM BP-5233 as the hybridoma that generates this antibody (see response page 5).

In response to this argument, while applicant has deposited the hybridoma expressing the anti-HM1.24 antibody, the specific promoter regions encompassed by the term "gene" have not been defined. As set forth in the previous office action the term "gene" includes not only the specific expression product but also any spliced intron regions and the regulatory sequences, enhancer sequences, and promoter regions. One of ordinary skill in the art would not be able to determine the specific regulatory sequences, enhancer sequences and promoter regions from the disclosed sequences of HM1.24 which appear to be only the specific coding regions of the antibody.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. The rejection of claims 15-19, 21, and 22 under 35 U.S.C. 102(b) as being anticipated by Morin, et al. (US PG PUB 2003/0211498, PCT filed April 1, 2001) is maintained.

The declaration under 37 CFR 1.132 filed July 14, 2009 is insufficient to overcome the rejection of claims 15-19, 21, and 22 based upon Morin, et al. as set forth in the last Office action because: the declaration is directed to the operability of the prior art, specifically regarding the use of the anti-HM1.24 antibody. The instant claims are drawn to the use of any antibody that binds to SEQ ID No. 2, not only the specific HM1.24 antibody. Morin, et al. teach ovarian tumor marker proteins including SEQ ID No. 2 (see sequence alignment in the office action mailed January 16, 2009). Morin, et al. also discloses the targeting of these tumor marker proteins for the inhibition of tumor growth and metastasis (abstract and paragraphs 72 and 87-91). Although Morin, et al. does not provide a specific working example targeting the polypeptide of SEQ ID No. 2 with an antibody, the complete disclosure of Morin, et al. supports the use and effectiveness of treating ovarian cancer by administering an antibody that binds to SEQ ID No. 2.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Conclusion

8. Claims 15-19, 21, 22, 26, and 27 are rejected.

Claims 24, 25, and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
November 2, 2009

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